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SECTION 5

510(K) SUMMARY
FOR
SIEMENS ARTIS ZEE FAMILY

FEB 11

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

November 19, 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**
Mr. Gary Johnson
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions USA, Inc
51 Valley Stream Parkway E-50
Malvern, PA 19355-1406
Phone:(601) 448-1778 Fax: (610) 448-1787

2. **Device Name and Classification**

Product Name:	Artis zee - Modular Angiographic System
Classification Name:	Angiographic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90 IZI

3. **Intended Use:**
Artis **zee / zeego** is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis **zee / zeego** family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, operating room angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures.

Artis **zee / zeego** can also support the acquisition of position triggered imaging for spatial data synthesis.

The intended use and indications for use of the Artis **zee / zeego** have minor changes from its predicate device the AXIOM Artis Modular Angiographic System.

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4. **Device Description:**
The Artis **zee / zeego** Modular Angiography System is designed as a set of components that may be combined into different configurations to provide specialized angiography systems. These models now will be equipped with a new user interface. In addition a new multi-axis stand will be offered.
The Artis **zee / zeego** Modular Angiography System is basically equal to the AXIOM Artis Modular Angiography System family with all its components.

5. **Substantial Equivalence:**
The Artis **zee/zeego** configurations are designed for fluoroscopy and acquisition of radiographic exposures of various anatomical regions of the body. They are substantially equivalent to the following Medical Devices:

510(k) Number	Date of Clearance	Device Name
K021021	June 06, 2002	MODULAR ANGIOGRAPHY SYSTEM AXIOM ARTIS
K052202	March 07, 2006	AXIOM ARTIS MODULAR ANGIOGRAPHY SYSTEM

The Indication for use of the Artis **zee/zeego** does not change from the above-mentioned Medical Devices.
A detailed Substantial Equivalence Comparison is provided in Section 12.

6. **Summary of Technological Characteristics of the Principal Device as compared with the Predicate Device:**
Artis **zee / zeego** Modular Angiography System is designed as a set of components (C-arm, X-ray tube and housing, flat detector, digital imaging system, collimator, generator etc.) that may be combined into different configurations to provide specialized angiography systems. Many of the components used with Artis **zee / zeego** are either commercially available with current Siemens systems or include minor modifications to existing components.

7. **General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Artis **zee / zeego** Modular Angiography System is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2008

Mr. Gary Johnson
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway MS E-50
MALVERN PA 19355-1406

Re: K073290
Trade/Device Name: Artis zee / zeego
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: January 21, 2008
Received: January 23, 2008

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510(k) Number (if known): K073290

Device Name: Artis zee / zeego

Indications for Use:

Artis zee / zeego is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis zee / zeego family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, operating room angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures.

Artis zee / zeego can also support the acquisition of position triggered imaging for spatial data synthesis.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073290